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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/708,006	11/08/2000	Akihiro Kishishita	197759US00CONT	1289

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OBLON SPIVAK MCCLELLAND MAIER & NEUSTADT PC  
FOURTH FLOOR  
1755 JEFFERSON DAVIS HIGHWAY  
ARLINGTON, VA 22202

EXAMINER

ZUCKER, PAUL A

ART UNIT PAPER NUMBER

1623

DATE MAILED: 12/04/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/708,006

Applicant(s)

KISHISHITA ET AL.

Examiner

Paul A. Zucker

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

1. This Office Action is responsive to Applicant's response in paper Nos. 9 and 10 to the first Office Action in Paper No. 7.
2. The receipt and entry of Applicant's amendment received 21 September 2001 is acknowledged and all previous objections to the specification and claims and rejections under 35 USC §112 are withdrawn.
3. The receipt and entry of Applicant's amendment received 11 August 2001 is acknowledged and the Examiner acknowledges that Applicant has met the requirements for receiving the benefit of an earlier filing date under 35 USC §120.
4. The receipt and entry of Applicant's Declaration under 37 CFR 1.132 filed 21 September 2001 is acknowledged.
5. The rejection of Claims 1 and 3-13 under 35 USC §102(b) as being anticipated by Nofre et al is hereby withdrawn in favor of the new rejection below. The rejection of Claim 2 is maintained for the reasons of record as set forth in the previous Office Action.

### ***Examiner's Response to Remarks***

3. Applicant has made an argument based on a stoichiometric analysis on page 6 in the third and fourth complete paragraphs of the amendment. While this argument appears convincing at first glance, two points cast doubt on its validity.
  - a. Applicant's argument makes the assumption that Nofre reports the weight of the Neotame obtained for the hydrate (or wet crystals) but reports the percent

Art Unit: 1623

yield for the anhydrate (or dry) crystals. This is an assumption without support in the disclosure of Nofre.

- b. Another more reasonable explanation for the weight/percent yield discrepancy is that it is due to rounding error in reporting the weight of the Neotame produced. It is standard scientific practice to assume an error in numbers of at least  $\pm 1$  unit in the least significant figure. Nofre's reported value for the yield of Neotame of 9 grams can be considered therefore to represent a range of 8-10 grams for the weight of Neotame obtained. In order for the discrepancy to be significant enough to support Applicant's stoichiometric analysis a yield of 9.0 grams would had to have been reported.
- c. Applicant's other arguments relate to the Declaration under 37 CFR. §1.132 and are addressed below.

***Declaration - 37 CFR § 1.132***

5. The Declaration under 37 CFR § 1.132 has been carefully considered and the following remarks are made in response thereto:

- a. Applicant has clearly demonstrated that Nofre discloses Neotame having a water content of 1.4 % (less than 3%) on page 2 of the Declaration, in numbered paragraph 6. This meets the limitation of Claim 2 which is therefore maintained.
- b. Applicant presents several other experiments in numbered paragraphs 7,8 and 9. These experiments employ Neotame/solvent ratios of approximately 1gram/milliliter and are not convincing demonstrations of

the disclosure of Nofre since such high compound/solvent ratios are never employed.

Thus the Declaration under 37 CFR 1.132 filed 21 September 2001 is insufficient to overcome the rejection of Claim 2 and based upon Nofre et al as set forth in the last Office action because it demonstrates that Nofre produces the end points of the range of water contents that Applicant's crystalline types fall within.

### ***New Rejections***

#### ***Claim Rejections - 35 USC § 112***

6. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 2 recite the limitation "(2 $\Theta$ , CuK $\alpha$ )" (in lines 3 and 5, respectively). The phrase "(2 $\Theta$ , CuK $\alpha$ )" renders the claim indefinite because it is unclear whether the limitations enclosed in parentheses are part of the claimed invention.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1623

7. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wakamatsu et al (US 4,810,818 03-1989) and further in view of Nofre et al (US 5,480,668 01-1996). Wakamatsu discloses (Column 3, lines 11-43) a method of producing a more easily soluble crystalline form of aspartame which comprises granulation and drying the aspartame to a water content of 2.6% by weight which meets the limitation of less than 3% of instant Claim 2. Wakamatsu further teaches (Column 2, lines 17-18) a range of granule size of 0.1 to 10 mm which embraces the instant range of 100-1,400  $\mu\text{m}$  (which corresponds to 0.1-1.4 mm). Wakamatsu is silent with respect to the use of N-[N-(3,3-dimethylbutyl)-L- $\alpha$ -aspartyl]-L-phenylalanine 1-methyl ester (neotame) in this process. Nofre, however, discloses (Column 4, line 65-Column 5, line 10) neotame and its synthesis (Column 6, lines 27-54) from aspartame to which it is a close analog. Nofre further teaches (Column 1, lines 10-19) the use of neotame as a sweetening agent in food and drinks as well as its use (Column 6, lines 16-26) in conjunction with other sweeteners such as sucrose and saccharin. Nofre further teaches (Column 6, lines 8-16) its use in conjunction with carriers or bulking agents such as polydextrose, starch, maltodextrins, and cellulose. Nofre teaches (Column 4, lines 29-37) the use of neotame for all uses of the known sweetener aspartame. Thus it would have been obvious for one of ordinary skill in the art to have performed this invention at the time Applicant asserts it was made. The motivation for performing this invention would have been to provide the same improved solubility for neotame that the process of Wakamatsu provided for its close analog aspartame, a commercially important

Art Unit: 1623

sweetener. Because of the very close structural similarity of neotame and aspartame and the large overlap in their intended uses the expectation for success would be very strong.

**Conclusion**

8. Claim 2 stands rejected under 35 USC §102(b). Claims 1-15 stand rejected under 35 USC §103(a).
9. Claims 1-15 are outstanding. Claims 1-15 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 703-306-0512. The examiner can normally be reached on Monday-Friday 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist can be reached on 703-308-1701. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



PAZ  
November 30, 2001

GARY GEIST  
SUPERVISORY PATENT EXAMINER  
TECH CENTER 1600